

REMARKS

This is a full and timely response to the outstanding Office Action mailed February 1, 2008. Claims 1, 2, 4-14, and 21-27 are pending in the application. Claims 1, 6, 14, 26 and 27 are amended herein. Applicant respectfully requests reconsideration and withdrawal of the rejections presented in the Office Action in view of the following remarks.

Rejections under 35 USC § 112

Claims 1, 2, 4-14, and 21-27 stand rejected under 35 USC § 112, second paragraph. Each of the rejections is addressed below.

1. The Office Action comments that "it is unclear in Claim 1 as to in which step, i.e. the forming step recited in b or the forming step recited in c, the calcium complex forming agent is present" (see Office Action at page 2, lines 15-17).

Applicant herein amends claim 1 to more clearly state that the calcium complex forming agent is present in step b) as the homogeneous mixture of milk protein material, hydrocolloid which precipitates with metal cations and water is formed.

2. The Office Action comments that "it is unclear in Claim 6 as to the meaning of the symbol '~'.

The symbol '~' has been replaced by the term 'about'.

3. The Office Action comments that "it is unclear in Claim 14 as to whether the applicant intends to recite a Markush group. Claim 14 is herein amended to put the claim language in Markush group format.

4. The Office Action comments that "it is unclear in Claim 21 as to the meaning of the phrase "in order to be finished."

Claim 21 is herein amended to remove this phrase.

5. The Office Action comments that "it is unclear in Claim 24 as "what the phrase "product formed with the aid of the method" entails. It is unclear as to if the method according to claim 1 is utilized in full or if the teachings of the method are encompassed in some other way."

Claim 24 is herein amended to remove the phrase "formed with the aid of," which is replaced by the phrase "obtained by."

6. The Office Action comments that "it is unclear in Claim 26 as to whether the applicant intends to recite a Markush group."

Claim 26 is herein amended to recite a Markush grouping.

7. The Office Action comments that "it is unclear in Claim 27 as to whether the applicant intends to recite a Markush group."

Claim 27 is herein amended to recite a Markush grouping.

Applicant therefore submits that the rejections to the claims under 35 USC § 112, second paragraph, have been traversed and respectfully request that this rejection now be withdrawn.

Rejections under 35 USC § 102(b)

A. Claims 1, 4, 9, 10, 14, 23, 24, and 25 stand rejected under USC 35 §102 (b) as allegedly being anticipated by *Tetsuo et al.* (US 3,627,536). Applicant respectfully traverses this rejection.

The Office Action asserts at pages 3-4 that the cited reference *Tetsuo*:

"teaches a method for the preparation of a meat substitute product which comprises protein, wherein: milk casein (i.e. a milk protein material), about 3% sodium alginate (i.e. a hydrocolloid which precipitates with metal cations), and water are combined, wherein the composition is formed into a homogenous mixture, the homogenous mixture is mixed with calcium chloride (i.e. a solution of metal cation with a valency of at least 2) to form a fibrous product, and the fibrous product is isolated. Refer specifically to Abstract, Column 2 lines 1-12, and Example I. *Tetsuo* teaches that phosphoric acid, (i.e. a calcium complex forming agent) is added to reduce the pH and form the fibrous product (Column 2 lines 13-18). *Tetsuo* teaches that flavoring is added to the homogenous mixture (Example 2)."

Applicant asserts that the cited reference at column 2, lines 1-25 teaches a process for preparing proteinaceous fibers that differs significantly from the methods as recited in the claims of the present application. The *Tetsuo* method comprises stirring a mixture of a protein, an alginate and water, and then adding a calcium solution to form a

semi-coagulated curd. An acid solution, preferably glacial acetic acid (*Tetsuo* at column 3, line 20) but which may be phosphoric acid, is subsequently added to decrease the pH to between about 3.2 to 2.4 to harden protein flakes, which are then thermally coagulated.

In contrast to the method taught by *Tetsuo*, the methods as recited in the claims of the present application comprise the steps of combining a protein material, a hydrocolloid which precipitates with metal cations and water to form into a homogenous mixture in the presence of a calcium complex-forming agent (step b). The homogenous mixture, including the calcium complex-forming agent, is then mixed with a solution of a metal cation with a valency of at least 2, to form a fibrous product.

The Office Action fails to identify where in *Tetsuo* a method is taught that involves use of a calcium complex-forming agent, for example a phosphate material. *Tetsuo* instead teaches use of an acid for lowering pH, not as a calcium-forming agent. Furthermore, *Tetsuo* fails to teach or suggest that Applicant's homogeneous mixture is to be formed in the presence of the calcium complex-forming agent, as recited in step (d) of Applicant's claim 1. Instead *Tetsuo* teaches that an acid is to be added after mixing protein, alginate and water to form a semi-coagulated protein curd and slicing the curd to form soft fibers. Upon introduction of the acid, the soft fibers sliced from the curd become harder and partially dewatered (see, Column 2, lines 17-18).

The *Tetsuo* reference, therefore, does not anticipate claim 1 of the present application. Claims 4, 9, 10, 14, 23, 24 and 25 depend directly or indirectly upon claim 1 and, thus, are likewise not anticipated by *Tetsuo*. Applicant therefore respectfully requests that this rejection be withdrawn.

B. Claims 1, 4, 5, 8, 9, 14, and 23-27 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Monsanto et al* (WO 9611 31 77). Applicant respectfully traverses the rejection.

The Office Action asserts at page 4 that

"Monsanto teaches a method for the preparation of a meat substitute product which comprises protein, wherein: powdered milk, which includes milk proteins and animal fat, about 0.1-1% gellan gum (i.e. a hydrocolloid which precipitates with metal cations), and water are combined, wherein the composition is formed into a homogenous mixture, the homogenous mixture is mixed with calcium chloride (i.e. a solution of metal cation with a valency of at least 2) to form a fibrous product, and the fibrous product is isolated. Refer specifically to Abstract, Page 5 lines 3-5 and 27-29, and Page 6 lines 10-21. Monsanto teaches that a phosphate, including

sodium hexametaphosphate, (i.e. a calcium complex forming agent) is added to form the fibrous product (Page 5 lines 29-34).

Applicant respectfully disagrees with this description of *Monsanto*. The *Monsanto* reference teaches methods of preparing heat stable, or non-melting, gellan gum pieces containing milk solids. *Monsanto* does not disclose any process in order to form a fibrous product and isolate the fibrous product as recited in claim 1. Furthermore, *Monsanto* does not disclose any process wherein a mixture of a milk protein material, a hydrocolloid which precipitates with metal cations and water is formed into a homogeneous mixture in the presence of a calcium complex-forming agent, as recited in claim 1 of the present application.

Monsanto, instead, teaches that sequestrants such as sodium phosphate can be dry blended with gellan gum prior to addition of gellan gum to water (see *Monsanto*, page 6, lines 29-31).

As seen, the methods and disclosure of the *Monsanto* reference teach away from the methods as claimed in the present application which are drawn to methods of forming and isolating fibrous milk-based protein products.

The *Monsanto* reference, therefore, does not anticipate Applicant's claim 1 or any of its dependent claims of the present application.

Applicant therefore respectfully requests that this rejection be withdrawn.

C. Claims 1, 4, 5, 7, 9-12, 14, and 23-26 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Shenouda* (US 4423083). Applicant respectfully traverses this rejection.

The Office Action asserts that

"Shenouda teaches a method for the preparation of a meat substitute product which comprises protein, wherein: whey protein or whole milk, which includes milk proteins and is a protein and water mixture, about 0.25-3% sodium alginate (i.e. a hydrocolloid which precipitates with metal cations), and water are combined, wherein the composition is formed into a homogenous mixture, the homogenous mixture is mixed with calcium chloride (i.e. a solution of metal cation with a valency of at least 2) to form a fibrous product, and the fibrous product is isolated. Refer specifically to Abstract, Column 1 lines 9-13, Column 2 lines 50-68, Column 3 lines 15-28, and Column 7 lines 1-20. Shenouda teaches that calcium complex forming agent is at least sufficient to form a complex with free calcium ions present (Column 7 lines 25-36 and Column 8 lines 15-37). Shenouda teaches that a phosphate, including sodium tripolyphosphate (i.e. a calcium complex forming agent) is added to form the final fibrous product (Column 8 lines 15-55). Shenouda teaches that flavoring and

fats can be added to the composition (Column 3 lines 1-14). *Shenouda* teaches that the pH of the composition is about 7 (Example 8)."

The *Shenouda* reference teaches a method of making a fibrous meat-like product that is significantly different from the methods as claimed in the present application. *Shenouda* teaches that a mixture of a protein, alginate and water are mixed and then *cooled* to form well-ordered ice crystals. The frozen mass of ice crystals is then partitioned, or sliced, into fiber bundles. To preserve the fibrous structure of the fiber bundles, and especially the outer surfaces thereof, the bundles are stabilized by melting and gelling the fiber bundles via infusion of gelation ions, for example with a salt (calcium) solution. The fiber bundles are then heat set. Next the texture of the fiber bundles is modified with a sequestering agent that controls the fiber quality by removing excess calcium ions not removed by a water wash, and also softens the meat-like product. Lastly, the fiber bundles are separated.

The methods of forming a fibrous protein product recited in the claims of the present application differ significantly from the method as taught by the *Shenouda* reference. In the methods according to the present claims, the protein solution, a hydrocolloid and water are mixed in the presence of a calcium complex-forming agent such as a phosphate into a homogeneous mixture, and *then* the homogeneous mixture is mixed with a solution of a metal cation with a valency of at least 2, for example with a calcium-containing solution. The fibers thus produced are homogeneous. This sequence of steps and the corresponding products, as presented in the claims of the present application, is not taught, or anticipated by the disclosure of *Shenouda*. For example, *Shenouda* does not mix its protein, alginate and water together in the presence of a calcium complex-forming agent. It does not introduce its sequestering agent until long after mixing its protein, alginate and water together.

Applicant therefore respectfully requests that this rejection be withdrawn.

Rejections under 35 USC § 103

A. Claims 2, 6, and 27

Claims 2, 6, and 27 stand rejected under 35 USC § 103(a) as being unpatentable over *Shenouda* (US 4,423,083). Applicant respectfully traverses this rejection. The Office Action asserts that;

"Shenouda teaches a method for the preparation of a meat substitute product as discussed above. Shenouda, however is silent to the method

as adding a calcium complex forming agent, i.e. phosphate, to the protein and water mixture, prior to adding the hydrocolloid which precipitates with metal cations, i.e. alginate, as recited in claim 2, to the number of sodium polyphosphate units as recited in claim 6, and to the phosphate material as trisodium phosphate as recited in claim 27.

Regarding the method as adding a calcium complex forming agent, i.e. phosphate, to the protein and water mixture, prior to adding the hydrocolloid which precipitates with metal cations, i.e. alginate, as recited in claim 2, it would have been obvious to switch the order of performing process steps, i.e. the order of the addition of the ingredients into the final mixture such as adding phosphate to the protein mixture prior to adding alginate, would be obvious absent any clear and convincing evidence and/or arguments to the contrary (MPEP 2144.04 [R-II]). 'Selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results'."

Referring to the specification of the present application (International Application Number: PCT/NL02/00594; Publication number WO 03/061400) at page 3, lines 9-13, adding of the calcium complex-forming agent in relation to the hydrocolloid which precipitates with metal cations can aid in providing better control over the homogeneous nature of the mixture. The order of adding the phosphate according to the present specification, and as recited in claim 2 of the present application is new and provides an unexpected homogenous product not disclosed, taught or suggested by the *Shenouda* reference.

Applicant therefore respectfully requests that this rejection of claim 2 be withdrawn.

Regarding claims 6 and 27, as amended herein, which are both dependent on claim 5 and indirectly dependent on independent claim 1, as stated above, *Shenouda* does not teach, disclose or suggest the method of claim 1, and hence does not render obvious claims 6 and 27.

Applicant therefore respectfully requests that this rejection with regard to claims 6 and 27 be withdrawn.

B. Claims 1, 4, 5, 11-13, and 23-26

Claims 1, 4, 5, 11-13, and 23-26 stand rejected under 35 USC § 103(a) as being unpatentable over *Visser et al.* (US 4,118,520) in view of *Shenouda*. Applicants respectfully traverse this rejection.

According to the Office Action, page 7, it would have been obvious to one of ordinary skill in the art to include sodium alginate as taught by *Shenouda* in the meat

substitute product disclosed in *Visser* "in order to form a thickener meat product with a thermally irreversible gel".

The present method facilitates preparation of a homogeneous mixture prior to precipitation with a multivalent metal cation solution to produce a fibrous product. In particular, the present method prevents premature precipitation of the hydrocolloid (page 3, lines 9-13). To achieve the aforementioned objective Applicant uses a calcium complexing agent and introduces said complexing agent before the addition of a multivalent metal cation solution.

In contrast *Visser et al.* describe a process for producing casein-containing mixed protein fibers, which comprises:

- (1) preparing an aqueous mixture containing:
 - (a) at least 30% protein based on total mixture weight, which protein consists of casein and at least one heat-settable protein;
 - (b) at least 0.1 mM calcium ions per gram of casein; and
 - (c) at least 0.04 mM orthophosphate ions per gram of casein,
- (2) spinning such mixture, at a temperature ranging from room temperature up to a temperature just below the mixture's gelling point, through the orifices of a spinneret into a gaseous medium, to obtain fibers; and
- (3) drying the fibers to a moisture content of less than 11%.

As acknowledged in the Office Action, *Visser et al.* are silent to the addition of a hydrocolloid which precipitates with metal cation. Furthermore, Applicant notes that *Visser et al.* fail to teach a process in which a fibrous product is formed by mixing a solution of a metal cation with a valency of at least 2 with a homogeneous mixture containing a protein material and water.

As mentioned herein before, *Shenouda* does not disclose a process in which a homogeneous mixture comprising protein material, precipitating hydrocolloid and water is prepared in the presence of a calcium complexing agent followed by mixing said mixture with a multivalent metal cation solution to produce a fibrous product. Although both *Visser et al.* and *Shenouda* are concerned with the preparation of proteinaceous fibres that can be used in meat substitutes, the processes taught by these two references are very different. *Visser et al.* teach a process in which an aqueous mixture of casein, calcium ions and orthophosphate is spun into a gaseous medium to obtain fibers. In contrast, *Shenouda* teaches a process in which a mixture comprising heat coagulable protein, alginate and water is frozen and sliced to form fiber bundles,

followed by infusion of gelation ions to reinforce the fiber-like structure, followed by heating, treatment with a sequestering agent and separation of the protein fiber bundles.

Since the processes taught by these references are so very different, Applicant disagrees that a skilled person would be inclined to try and combine the teachings of these publications. Furthermore, even if a skilled person were to combine the teachings of these two documents, such attempted combination would not render obvious the method as recited in present claim 1.

In order to illustrate the differences between on the one hand the teachings of *Visser et al* and *Shenouda* and on the other hand the method as recited in the present claim 1, we have summarized the main processing steps of each in the following table:

	Visser et al	Shenouda	Claim 1
1	Combine casein and calcium ions (column 2, lines 16-19)	Combine protein, alginate and water	Prepare homogeneous mixture of protein, hydrocolloid and water in presence of Ca complexing agent
2	Add orthophosphate	Freeze and slice to form fiber bundles	Add solution of metal cation to form fibrous product
3	Spin into gaseous medium to produce fibers	Infuse fiber bundles with gelation ions	Isolate fibrous product
4	Dry to a moisture content of less than 11%	Heat to coagulate protein	
5		Treat with sequestering agent	
6		Separate protein fiber bundles	

As evident from the above table, for a skilled person to arrive at the subject matter of present claim 1, *Shenouda* should motivate such a person to modify the process taught by *Visser et al.*, for example by: - introducing alginate in step 1; and - postponing the addition of the calcium ions until after the addition of the orthophosphate. This would not answer the questions, however, of when to add orthophosphate (*Visser et al.*) or a sequestering agent (*Shenouda*) and whether to form fibers by spinning (*Visser et al.*) or by freezing and slicing (*Shenouda*).

It would only be with the benefit of hindsight that *Shenouda* would motivate a skilled person to modify the process taught by *Visser et al.* in this fashion. In addition,

Applicant notes that the assertion in the Office Action that it would have been obvious to include sodium alginate as taught by *Shenouda* in the meat substitute product disclosed in *Visser* "in order to form a thickener meat product with a thermally irreversible gel" starts from the assumption that it would somehow be beneficial to achieve the latter objective. However, in the absence of any data suggesting that the fibers disclosed by *Visser et al.* need to be thickened, Applicant disputes that there would be an incentive for a skilled person to pursue this objective. Finally, Applicant notes that column 2, lines 52-55 of *Visser et al.* teaches that the dried fibers must be produced in non-gelled form so they will gel when rehydrated in water of a temperature above the heat-setting temperature of the protein. Consequently, it would go against the teachings of *Visser et al.* to produce fibers that contain an alginate gel. Thus, the subject matter of the present claims is non-obvious with respect to the disclosures of *Visser et al.* and *Shenouda*.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

C. Claims 21 and 22

Claims 21 and 22 stand rejected under 35 USC § 103(a) as being unpatentable over *Tetsuo et al.* in view of *Lusas et al.* (US 5,300,312). Applicant respectfully traverses this rejection.

As stated in this Response at pages 6-7, Applicant asserts that the cited reference of *Tetsuo* does not teach, disclose or suggest the combination of elements as claimed in the independent claim 1 of the present application. Accordingly, *Tetsuo*, even in combination with *Lusas*, does not teach, disclose or suggest the subject matter of the claims 21 and 22 of the present application. Applicant therefore respectfully requests that this rejection be withdrawn.

D. Claims 21 and 22

Claims 21 and 22 were rejected under 35 USC § 103(a) as being unpatentable over *Monsanto* in view of *Lusas et al.* (US 5,300,312). Applicant respectfully traverses this rejection.

As stated in this Response at pages 7-8, Applicant asserts that the cited reference of *Monsanto* does not teach, disclose or suggest the combination of elements as claimed in the independent claim 1 of the present application. Accordingly, *Monsanto*, even in combination with *Lusas*, does not teach, disclose or suggest the

subject matter of the claims 21 and 22 of the present application. Applicant therefore respectfully requests that this rejection be withdrawn.

CONCLUSION

In light of the foregoing amendments to the claims and specification and for at least the reasons set forth above, Applicant respectfully submits that all objections and/or rejections have been traversed, rendered moot, and/or accommodated. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested.

Furthermore, any and all findings of well-known art and official notice, or statements interpreted similarly, should not be considered well known since the Office Action does not include specific factual findings predicated on sound technical and scientific reasoning to support such conclusions.

If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,



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